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APPLICATION NO. FILING DATE		NG DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/508,661	09/508,661 05/26/2000		JEAN-PIERRE SACHETTO		6789
2292	7590	01/28/2004		EXAMINER	
		OLASCH & BII	GEORGE, KONATA M		
PO BOX 74'		22040-0747	ART UNIT	PAPER NUMBER	
THEE CIT	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	22010 0111		1616	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<u> </u>		Арр	lication No.	Applicant(s)					
Office Action Summary			09/508,661 SACHETTO ET AL.						
			niner	Art Unit					
		Kona	ata M. George	1616					
Period fo	The MAILING DATE of this commu or Reply	nication appears o	on the cover sheet v	vith the correspondence addi	ess				
THE I - External after - If the control of the cont	ORTENED STATUTORY PERIOD MAILING DATE OF THIS COMMUN nsions of time may be available under the provision SIX (6) MONTHS from the mailing date of this come period for reply specified above is less than thirty period for reply is specified above, the maximum are to reply within the set or extended period for reply received by the Office later than three months and patent term adjustment. See 37 CFR 1.704(b).	IICATION.  Is of 37 CFR 1.136(a). In  Imunication.  (30) days, a reply within the  Istatutory period will apply  Ity will, by statute, cause the	no event, however, may a he statutory minimum of th and will expire SIX (6) MC he application to become A	reply be timely filed irty (30) days will be considered timely.  NTHS from the mailing date of this com  ABANDONED (35 U.S.C. § 133).	munication.				
1)	Responsive to communication(s) fi	led on <i>15 October</i>	- 2003.						
, <del></del>		2b)⊠ This action							
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Dispositi	on of Claims				·				
	Claim(s) <u>1-3,6,15,22-27,33,37-39,42,43 and 45-55</u> is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  Claim(s) <u>1-3,6,15, 37-39, 42, 43 and 45</u> is/are allowed.								
7) 🖂	Claim(s) <u>22-27,33 and 46-55</u> is/are rejected. Claim(s) <u>23</u> is/are objected to. Claim(s) are subject to restriction and/or election requirement.								
	on Papers								
	The specification is objected to by the drawing(s) filed on is/are Applicant may not request that any objected Replacement drawing sheet(s) including	e: a) accepted ection to the drawing	g(s) be held in abeya	nce. See 37 CFR 1.85(a).	1.121(d).				
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.									
Priority u	inder 35 U.S.C. §§ 119 and 120		*						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> <li>13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.</li> <li>37 CFR 1.78.</li> <li>a) The translation of the foreign language provisional application has been received.</li> <li>14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.</li> </ul>									
Attachment			_						
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review ( nation Disclosure Statement(s) (PTO-1449) I			Summary (PTO-413) Paper No(s). Informal Patent Application (PTO-1:					

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#### **DETAILED ACTION**

Claims 1-3, 6, 15, 22-27, 33, 37-39, 42, 43 and 45-55 are pending in this application.

#### **Action Summary**

- 1. Examiner acknowledges the cancellation of claims 5, 7-14, 16-21, 28, 29, 32, 35, 36, 40 and 41 and the addition of claims 53-55. Therefore, all rejections directed towards cancelled claims are hereby withdrawn.
- 2. The rejection of claims 30 and 33 under 35 U.S.C. 102(b) as being anticipated by Slagel is hereby withdrawn.
- 3. The rejection of claims 30, 33 and 37 under 35 U.S.C. 103(a) over Slagel is hereby withdrawn.

#### Restriction/Election

4. Claims 8, 10, 12-14, 28-30, 32, 33, 36, 37, 40 and 41 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 1-3, 6, 15, 22-27, 38, 39, 42 and 43, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 1-3, 6, 15, 22-27, 38, 39, 42 and 43 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made is hereby withdrawn.

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#### Claim Objections

5. Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 23 depends upon a later claim (claim 33), which is improper.

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 22-27, 33 and 46-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph have been described in *In Re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it

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is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

### (1) The nature of the invention:

The invention is directed towards the treatment of prophylaxis (i.e. prevention) of inflammatory bowel disease (IBD) comprising disease mucosa of the gastrointestinal tract with a therapeutic amount of a polysaccharide.

(2) The state of the prior art:

The prior art teaches using polysaccharides in compositions to treat IBD however, not as the sole therapeutic agent.

(3) The relative skill of those in the art:

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art:

The art pertaining to the prophylaxis of IBD remains highly unpredictable. While it is known to treat IBD the prophylaxis however, is not.

(5) The breadth of the claims:

The claims are narrow.

(6) The amount of direction or guidance presented:

The specification provides direction or guidance by way of examples with respect to treating IBD however, not for the prophylaxis of IBD.

(7) The presence or absence of working examples:

The specification provides direction or guidance by way of examples with respect to treating IBD however, not for the prophylaxis of IBD.

(8) The quantity of experimentation necessary:

The specification did enable any person skilled in the art to which it pertains to use the invention commensurate in scope with this claim. The skilled artisan would have numerous factors to consider when trying to prevent IBD.

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## Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George

THURMAN-K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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